DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 24, 2014

Teleflex Medical
Amanda Webb
Senior Regulation Affairs Specialist
2917 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K141940
Trade/Device Name: Concha Smart Column
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: II
Product Code: BTT
Dated: October 27, 2014
Received: October 29, 2014

Dear Amanda Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ConchaSmart Column

Indications for Use *(Describe)*
When used with a Neptune Heated Humidifier and Hudson RCI ventilator circuits, the ConchaSmart Column provides heated humidification for patients with and without an artificial airway in place.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8050
Fax: 919-433-4996

B. Contact Person

Amanda Webb
Senior Regulatory Affairs Specialist

C. Date Prepared

July 14, 2014

D. Device Name

Trade Name:	ConchaSmart Column
Common Name:	Respiratory Gas Humidifier
Product Code:	BTT
Regulation Number:	868.5450
Classification:	II
Classification Panel:	Anesthesiology

E. Predicate Device

This submission demonstrates substantial equivalence to the Fisher and Paykel MR290 Autofeed Humidification Chamber K131957.

F. Device Description

The ConchaSmart Column is an accessory to the Neptune Heated Humidifier (K063758 and K131912). It is a single use, disposable humidifier cartridge which is intended for neonatal, infant, pediatric, and adult patients requiring heated humidification. The ConchaSmart Column is used by inserting the column into the center of the Neptune Heated Humidifier.

G. Indications for Use

When used with the a Neptune Heated Humidifier and Hudson RCI ventilator circuits, the ConchaSmart Column provides heated humidification for patients with and without an artificial airway in place.

H. Technological Characteristics Comparison to the predicate

Comparative Characteristics	Fisher and Paykel MR290 Autofeed Humidification Chamber K131957	ConchaSmart Column
Intended Use	When used with Fisher and Paykel heated humidifiers cleared in K132017, K131957, K131895, and K110019 the MR290 provides heated humidification for patients with and without an artificial airway in place.	When used with a Neptune Heated Humidifier and Hudson RCI ventilator circuits, the ConchaSmart Column provides heated humidification for patients with and without an artificial airway in place.
Patient Population	Neonatal, Infant, Pediatric, Adult	Neonatal, Infant, Pediatric, Adult
Humidification Therapies	Invasive, Non-Invasive, High Flow Nasal Cannula Therapy	Invasive, Non-Invasive, High Flow Nasal Cannula Therapy
Humidity Output	ISO 8185:2007 Subglottic mode: (≥33mg H_2O /L) Supraglottic mode: (≥10mg H_2O /L)	ISO 8185:2007 Subglottic mode: (≥33mg H_2O /L) Supraglottic mode: (≥10mg H_2O /L)
Enthalpy Limit	ISO 8185:2007 < 194 kJ/kg dry gas	ISO 8185:2007 < 194 kJ/kg dry gas
Leakage	< 100 ml/min	≤ 29 ml/min
Compressible Volume	280 ml	190 ml
Compliance	0.4ml/cmH_2O	0.25ml/cmH_2O
Connectors	ISO 5356-1:2004 compliant 22 mm connectors	ISO 5356-1:2004 compliant 22 mm connectors
Sterilization	Non-Sterile	Non-Sterile
Shelf Life	No Shelf Life	3 year
Materials	The materials were cleared as having met ISO 10993 and G-95-1 requirements	The materials were cleared as having met ISO 10993 and G-95-1 requirements

As evidenced by the comparison table above the ConchaSmart Column is the same as the predicate device in many ways, the same intended use, the same operating principles, and the same scientific fundamental technology. The primary differences relate to performance specifications in which the ConchaSmart Column contains less dead space, less compliance, and more stringent leak specifications. In addition the ConchaSmart Column is labeled with a shelf life, whereas the MR290 is not.

I. Performance Data

The change in sterility does not impact the performance characteristic of the device; therefore, no performance testing was required.

J. Conclusion

The data presented demonstrate that the device is as safe and as effective as the predicate device and therefore substantially equivalent.